

REMARKS

The pending final Office Action addresses and rejects pending claims 1-21 and 24-52. Claims 22 and 23 are cancelled. Applicants respectfully request that the amendments submitted herein after final be entered and considered as they do not raise any new issues.

Claim Amendments

Applicants amend independent claims 1 and 5 to recite an elongated member having a distal effector portion and a proximal controlling portion such that a first tissue engaging member and a second tissue engaging member are disposed on the distal effector portion of the elongated member. Support for this amendment can be found throughout the specification and in the drawings, for example in paragraphs [0113] and [0171] and illustrated in FIG. 26 and FIG. 30. Dependent claims 3, 18, and 45 are amended to correspond to amended claims 1 and 5. Dependent claim 47 is amended to recite a "torsion spring." Support for this amendment can be found in paragraphs [0171], [0176], and [0179] of the application.

Applicants amend independent claim 34 to recite an apparatus having a *substantially rigid* elongated member. Support for this amendment can be found throughout the specification and in the drawings, at least in paragraph [0083] and in FIGS. 25, 30, and 36.

Applicants add new independent claim 53, support for which can be found in claim 24. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. §112

Claim 47 is rejected pursuant to 35 U.S.C. §112, first paragraph, as failing to comply with the written description. The Examiner argues that the specification does not describe a "leaf spring" as a part of the claimed invention. Applicants amend dependent claim 47 to recite a "torsion spring," thereby obviating the basis for the Examiner's objection.

Claim Rejections Pursuant to 35 U.S.C. §102

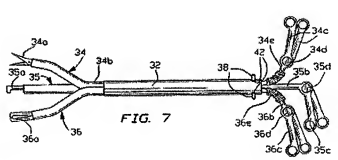
Wilk

Claims 1-3, 5-7, 9, 17, 18, 20, 24, 25, 27-30, 45, and 49-51 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,395,367 of Wilk. Applicants respectfully disagree.

Independent Claims 1 and 5

Independent claims 1 and 5, as amended, recite a tissue shaping instrument comprising an elongated member having a distal effector portion and a proximal controlling portion. A first tissue engaging device and a second tissue engaging device are disposed on the distal effector portion of the elongated member. Wilk is directed to a laparoscopic device that can have multiple laparoscopic instruments inserted into a rigid access sleeve to perform surgery as needed within a trocar or cannula. The Examiner points to FIG. 7 of Wilk, which is reproduced

herein, and col. 9, line 44 to col. 10, line 55 of Wilk as teaching the claimed device. This specified section and FIG. 7 of Wilk illustrate an embodiment in which three



individual laparoscopic instruments (34, 35, 36) are inserted into a sleeve (32) such that each instrument (34, 35, 36) exits the sleeve (32) on one end of the device while leaving its actuating mechanism on an opposite end of the device. The three instruments remain separate and distinct and are simply inserted within and through the sleeve.

Wilk cannot meet the requirements of claims 1 and 5 because Wilk does not teach or suggest an elongated member with first and second tissue engaging devices *disposed on a distal effector portion of the elongated member*. The Examiner points to sleeve (32) and/or central shafts (34b, 35b, 36b) as being the elongated member of claims 1 and 5. None of these elements, however, meet the requirements of the claims. Claims 1 and 5 require that the first and second tissue engaging

devices must be *disposed on* the distal effector portion of the elongated member. Sleeve (32) does not have a distal effector portion having first and second tissue engaging devices disposed thereon because the sleeve (32) is simply a hollow access device through which the instruments (34, 35, 36) are passed. The instruments (34, 35, 36) are not disposed anywhere on the sleeve (32) and in fact, are not located anywhere near the sleeve (32) because they are formed on the ends of central shafts (34b, 35b, and 36b) which extend through the sleeve (32).

Further, each central shaft (34b, 35b, and 36b) has a *single* operative tip (34a, 35a, 36a) disposed at an end thereof. There is no teaching or suggestion in Wilk of any operative tip that has both a first tissue engaging device *and* a second tissue engaging device *with opposed articulable arms*. At most, one operative tip (34a) or (34b) may include opposed arms, but does not also include an entire additional tissue engaging device. Wilk thus fails to teach or suggest any elongates member with a distal effector portion having first and second tissue engaging devices disposed thereon and thus cannot anticipate claims 1 and 5. Accordingly, claims 1 and 5, as well as claims 2, 3, 6, 7, 9, 17, 18, 20, 45, and 49-51 which depend therefrom, distinguish over Wilk and represent allowable subject matter.

Independent claim 24

Independent claim 24 requires a first member having a first securing part, a second member having a second securing part, and an actuating mechanism operatively linking the first and second members to facilitate simultaneous dependent movement of the members to draw together first and second stomach tissue sections. Wilk does not anticipate claim 24 because Wilk fails to teach or suggest an actuating mechanism that both *operatively links* first and second members and allows *simultaneous dependent* movement of first and second members. As noted above, Wilk only discloses separate instruments that are not operatively linked, for example, the separate instruments (34, 35, 36) as shown above in FIG. 7. These three instruments (34, 35, 36) are not operatively linked together, but remain completely separate and distinct within the sleeve (32). So while these instruments may be considered to be capable of dependent movement, they are not operatively linked. In addition, while a single operative tip of Wilk may have two portions which are linked

together (i.e., tips (34a) or (36a)), none of the tips disclosed in Wilk are capable of simultaneous *dependent* movement. Thus, Wilk cannot anticipate claim 24 because Wilk fails to teach or suggest an actuating mechanism that *both* operatively links first and second members and allows for simultaneous dependent movement of the first and second members. Accordingly, claim 24, as well as new claim 53 which recites similar requirements as claim 24, and claims 25 and 27-30 which depend from claim 24, distinguish over Wilk and represent allowable subject matter.

Kuehn

Claims 34, 35, 37, and 39-44 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,695,866 of Kuehn et al. ("Kuehn"). Applicants respectfully disagree.

Independent claim 34, as amended, requires an apparatus having a substantially rigid elongated member. Kuehn is directed to a device for mitral and tricuspid valve repair. The Examiner points to cardiac catheter (126) of Kuehn as being the claimed elongated member. The cardiac catheter (126), as with all catheters, must be flexible so that it can be guided through the body to the needed location, whether through veins, arteries, or through heart musculature. *See col. 6, lines 30-35*. Further, Kuehn does not teach or suggest the use of anything but a flexible catheter. A substantially rigid catheter (126) would render the device of Kuehn unusable for its intended purpose of repairing heart valves. Accordingly, at least because Kuehn fails to disclose a substantially rigid elongated member, claim 34 as well as claims 35, 37, and 39-44 which depend therefrom, distinguish over Kuehn and represent allowable subject matter.

Claim Rejections Pursuant to 35 U.S.C. §103

Wilk and McGarry

Claims 4, 10-13, 21, and 31-33 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,289,963 of McGarry et al. ("McGarry"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to

disclose certain limitations as recited in these claims. Thus, the Examiner relies on McGarry to disclose these limitations. McGarry is directed to a surgical stapler having a single stapling device at one end of an elongate member. McGarry, however, fails to remedy the deficiencies of Wilk with regard to independent claims 1, 5, and 24, from which claims 4, 10-13, 21, and 31-33 depend. In particular, McGarry does not teach or suggest an elongated member with a distal effector portion having first and second tissue engaging devices disposed thereon, as required by claims 1 and 5. Nor does McGarry teach or suggest an actuating mechanism that both operatively links first and second members and allows simultaneous dependent movement of first and second members. Accordingly, claims 4, 10-13, 21, and 31-33 distinguish over the combination of Wilk and McGarry at least because they depend from an allowable base claim.

Wilk and McPherson

Claims 8, 26, 36, 38, and 52 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al. ("McPherson"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in these claims. Thus, the Examiner relies on McPherson to disclose these limitations. McPherson is directed to a surgical retractor having a coiled screw at one end of the device. McPherson, however, fails to remedy the deficiencies of Wilk with regard to independent claims 5 and 24, from which claims 8, 26, 36, 38, and 52 depend. In particular, McPherson does not teach or suggest an elongated member with a distal effector portion having first and second tissue engaging devices disposed thereon, as required by claim 5. Nor does McPherson teach or suggest an actuating mechanism that both operatively links first and second members and allows simultaneous dependent movement of first and second members. Accordingly, claims 8, 26, 36, 38, and 52 distinguish over the combination of Wilk and McPherson at least because they depend from an allowable base claim.

Wilk and Kuehn

Claim 14 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kuehn. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose at least one tissue fixation device that is a two-part fastener. Thus, the Examiner relies on Kuehn to disclose such a tissue fixation device. As noted above, Kuehn is directed to a device for mitral and tricuspid valve repair. Kuehn, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 14 depends. In particular, Kuehn does not teach or suggest an elongated member with a distal effector portion having a first tissue engaging device and a second tissue engaging device with opposed articulable arms disposed thereon, as required by claim 5. Accordingly, claim 14 distinguishes over the combination of Wilk and Kuehn at least because it depends from an allowable base claim.

Wilk and Kammerer

Claims 15 and 16 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kammerer. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 15 and 16. Thus, the Examiner relies on Kammerer to disclose these limitations. Kammerer is directed to an H-type fastener for tissue. Kammerer, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claims 15 and 16 depend. In particular, Kammerer does not teach or suggest an elongated member with a distal effector portion having a first tissue engaging device and a second tissue engaging device with opposed articulable arms disposed thereon, as required by claim 5. Accordingly, claims 15 and 16 distinguish over the combination of Wilk and Kammerer at least because they depend from an allowable base claim.

Wilk and Yoon

Claim 19 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,954,731 of Yoon. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose a viewing endoscope. Thus, the Examiner relies on Yoon to disclose such an endoscope. Yoon is directed to a surgical instrument with multiple rotatably mounted spreadable end effectors. Yoon, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 19 depends. In particular, Yoon does not teach or suggest an elongated member with a distal effector portion having a first tissue engaging device and a second tissue engaging device with opposed articulable arms disposed thereon, as required by claim 5. Accordingly, claim 19 distinguishes over the combination of Wilk and Yoon at least because it depends from an allowable base claim.

Wilk and Iacovelli

Claims 46 and 48 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,350,391 of Iacovelli. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 46 and 48. Thus, the Examiner relies on Iacovelli to disclose these limitations. Iacovelli is directed to a laparoscopic scissors device but fails to remedy the deficiencies of Wilk with regard to independent claim 1, from which claims 46 and 48 depend. In particular, Iacovelli does not teach or suggest an elongated member with a distal effector portion having a first tissue engaging device and a second tissue engaging device with opposed articulable arms disposed thereon, as required by claim 1. Accordingly, claims 46 and 48 distinguish over the combination of Wilk and Iacovelli at least because they depend from an allowable base claim.

Conclusion

In view of the above remarks, Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

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